AUG - 2 2011

SIGMA
MEDICAL SUPPLIES CORP

510 (K) Summary
For
SIGMA Sterilization Pouch and Roll

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Summary Date: January 3, 2011

1. Device Name

Trade Name:	SIGMA Sterilization Pouch and Roll
Common/usual Name:	SIGMA Sterilization Pouch and Roll
Device Classification Names:	1) Sterilization wraps containers, trays, cassettes & accessories. 2) Indicator, Physical/Chemical Sterilization Process
Classification/Panel:	Class II, 21 CFR 880.6850 & 21 CFR 880.2800
Classification Advisory Committee:	General Hospital
Product Code:	1) FRG 2) JOJ
Recognized Performance Standard	1) ANSI/AAMI/ISO 11607-1:2006 (KCT) 2) ISO 11140-1:2005 (JOJ)

2. Predicate Devices

- K070428, Medicom Self Sealing - Sterilization Pouch, Product Code [KCT; JOJ]
- K051242, Winner® Self Seal Sterilization pouch, Product Code [KCT]

3. Intended Use

The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 3 years post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.

The SIGMA sterilization pouch and roll is offered in the following 5 types:

- Self-sealing sterilization pouches
- Sterilization pouches, Flat
- Sterilization pouches, Gusseted
- Sterilization rolls, Flat
- Sterilization rolls, Gusseted

The defining characteristics of the 5 types as follows:

- **Self-sealing sterilization pouches:** These pouches are made from a medical grade plastic film that is heat sealed on three sides. The forth side has an adhesive strip that is used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas.
- **Sterilization pouches, Flat:** These pouches has the same components with the Self-sealing sterilization pouches, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using.
- **Sterilization pouches, Gusseted:** These pouches are the same with the Sterilization pouches, flat, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.
- **Sterilization rolls, Flat:** These rolls are made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the self-sealing sterilization pouches.
- **Sterilization rolls, Gusseted:** These rolls are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.

The following table (**Table 2-1**) lists the model numbers of the SIGMA sterilization pouch and roll by type, model, dimension and characteristics:

Table 2-1 The model numbers of SIGMA sterilization pouch and roll (Type, Model, Dimension and Characteristics)

Type	Model	Dimension in S.I.	Characteristics
Self-Sealing Sterilization Pouches	SMSE057133	57 mm × 133 mm	These pouches are made from a medical grade plastic film that is heat-sealed on three sides. The forth side has an adhesive strip that is paper and used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas.
	SMSE090162	90 mm × 162 mm	
	SMSE070257	70 mm × 257mm	
	SMSE090257	90 mm × 257 mm	
	SMSE135283	135 mm × 283 mm	
	SMSE180335	135 mm × 335 mm	
	SMSE190358	190 mm × 358 mm	
	SMSE300380	300 mm × 380 mm	
	SMSE300474	300 mm × 474 mm	

Sterilization Pouches, Flat	SMFP075200	75 mm × 200 mm	These pouches has the same components with the Self-sealing sterilization pouches, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using.
	SMFP075300	75 mm × 300 mm	
	SMFP100200	100 mm × 200 mm	
	SMFP100300	100 mm × 300 mm	
	~~SMFP150300~~	~~150 mm × 300 mm~~	
	SMFP200400	200 mm × 400 mm	
	SMFP250450	250 mm × 450 mm	
	SMFP300500	300 mm × 500 mm	
Sterilization Pouches, Gusseted	SMGP100300	100 mm × 40 mm× 300 mm	These rolls are the same with the Sterilization pouches, flat, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.
	SMGP150400	150 mm × 50 mm× 400 mm	
	SMGP200400	200 mm × 50 mm× 400 mm	
	SMGP250480	250 mm × 60 mm× 480 mm	
	SMGP300500	300 mm × 70 mm× 500 mm	
Sterilization Rolls, Flat	SMFR 022	50 mm × 200 M	~~These rolls are made from a medical~~ grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the self-sealing sterilization pouches.
	SMFR 032	75 mm × 200 M	
	SMFR 042	100 mm × 200 M	
	SMFR 062	150 mm × 200 M	
	~~SMFR 082~~	~~200 mm × 200 M~~	
	SMFR 102	250 mm × 200 M	
	SMFR 122	300 mm × 200 M	
	SMFR 142	350 mm × 200 M	
	SMFR 162	400 mm × 200 M	
Sterilization Rolls, Gusseted	SMGR 031	75 mm × 35 mm ×100 M	These rolls are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.
	SMGR 041	100 mm × 40 mm ×100M	
	~~SMGR 061~~	~~150 mm × 50 mm ×100 M~~	
	SMGR 081	200 mm × 50 mm ×100 M	
	SMGR 101	250 mm × 60 mm ×100 M	
	SMGR 121	300 mm × 70 mm ×100 M	
	SMGR 141	350 mm × 80 mm ×100 M	
	SMGR 161	400 mm × 80 mm ×100 M	

4. 510(k) Statement

A 510(k) statement for the new device, as required by 21 CFR 93, is replaced with this 510(k) summary.

5. Proposed Labeling

A comparison with the predicate labeling confirms our claim of substantial equivalence with the predicate. A draft copy of the proposed and predicate device labeling may be found in Section 13.

6. Device Description

The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 3 years post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.

The SIGMA sterilization pouch and roll is offered in the following 5 types:

- **Self-sealing sterilization pouches:** These pouches are made from a medical grade plastic film that is heat sealed on three sides. The forth side has an adhesive strip that is used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas.
- **Sterilization pouches, Flat:** These pouches has the same components with the Self-sealing sterilization pouches, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using.
- **Sterilization pouches, Gusseted:** These pouches are the same with the Sterilization pouches, flat, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.
- **Sterilization rolls, Flat:** These rolls are made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the self-sealing sterilization pouches.
- **Sterilization rolls, Gusseted:** These rolls are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.

The following table (**Table 2-2**) lists the model numbers of the SIGMA sterilization pouch and roll by type, model, and dimension:

Table 2-2 The model numbers of SIGMA sterilization pouch and roll (Type, Model and Dimension)

Type	Model	Dimension in S.I.
Self-Sealing Sterilization Pouches	SMSE057133	57 mm × 133 mm
	SMSE090162	90 mm × 162 mm
	SMSE070257	70 mm × 257mm
	SMSE090257	90 mm × 257 mm
	SMSE135283	135 mm × 283 mm
	SMSE180335	135 mm × 335 mm
	SMSE190358	190 mm × 358 mm
	SMSE300380	300 mm × 380 mm
	SMSE300474	300 mm × 474 mm

Sterilization Pouches, Flat	SMFP075200	75 mm × 200 mm
	SMFP075300	75 mm × 300 mm
	SMFP100200	100 mm × 200 mm
	SMFP100300	100 mm × 300 mm
	SMFP150300	150 mm × 300 mm
	SMFP200400	200 mm × 400 mm
	SMFP250450	250 mm × 450 mm
	SMFP300500	300 mm × 500 mm
Sterilization Pouches, Gusseted	SMGP100300	100 mm × 40 mm× 300 mm
	SMGP150400	150 mm × 50 mm× 400 mm
	SMGP200400	200 mm × 50 mm× 400 mm
	SMGP250480	250 mm × 60 mm× 480 mm
	SMGP300500	300 mm × 70 mm× 500 mm
Sterilization Rolls, Flat	SMFR 022	50 mm × 200 M
	SMFR 032	75 mm × 200 M
	SMFR 042	100 mm × 200 M
	SMFR 062	150 mm × 200 M
	SMFR 082	200 mm × 200 M
	SMFR 102	250 mm × 200 M
	SMFR 122	300 mm × 200 M
	SMFR 142	350 mm × 200 M
	SMFR 162	400 mm × 200 M
Sterilization Rolls, Gusseted	SMGR 031	75 mm × 35 mm ×100 M
	SMGR 041	100 mm × 40 mm ×100M
	SMGR 061	150 mm × 50 mm ×100 M
	SMGR 081	200 mm × 50 mm ×100 M
	SMGR 101	250 mm × 60 mm ×100 M
	SMGR 121	300 mm × 70 mm ×100 M
	SMGR 141	350 mm × 80 mm ×100 M
	SMGR 161	400 mm × 80 mm ×100 M

7. Description of Comparison and Substantial Equivalence

A summary of the technological characteristics of the device subject of this premarket notification in comparison to those of the predicate devices is included in **Table 2-3.**

Table 2-3 Summary of the Proposed and Predicate Devices Technological Characteristics

Device	New Device		Predicate devices			
Device name	SIGMA sterilization pouch and roll		Medicom® Self Sealing sterilization pouch		Winner® Self Seal Sterilization pouch	
510(k) Number	K102158		K070428		K051242	
Material Composition	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator Print Ink		Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator Print Ink		Medical Grade paper, PP, PE, PU adhesive, EO and Steam Process Indicator Print Ink	
Intended use	The sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 3 years post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.		The self-sealing sterilization pouches are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 100 – 120 minutes at 50 0C with a relative humidity between 60 - 85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch maintains the enclosed devices sterile up until one-year post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.		Winner® Self Seal Sterilization Pouches are intended to be used to enclose another medical device that is to be sterilized by a health provider by steam 121°C for 15 minutes or ethylene oxide (EtO). It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	
Device models (Configurations/Dimensions)	Model	Description	Product Code	Description	Model	Description
	SMSE057133	57mm × 133mm	68015	35mm x 73mm	N/A	76mm x 203mm
	SMSE090162	70mm × 257mm	68000	49mm x 200mm		89mm x 203mm
	SMSE070257	90mm × 162mm	88015	57mm x 100 mm		89mm x 229mm
	SMSE090257	90mm × 257mm,	68005	62mm x 103mm		89mm x 559mm
	SMSE135283	135mm × 283mm	68020	62mm x 220mm		102 mmx 203mm
	SMSE180335	135mm × 335mm	68010	69mm x 200mm		102mm x 279mm
	SMSE190358	190mm × 358mm	88000	70mm x 229 mm		102 mmx 559mm
	SMSE300380	300mm × 380mm	88005	89mm x 133 mm		127mm x 381mm
	SMSE300474	300mm × 474mm	88010	89mm x 229 mm		133mm x 254mm
	SMFP075200	75 mm × 200 mm	68025	116mm x 219mm		191mm x 330mm
	SMFP075300	75 mm × 300 mm	88025	133 mm x 254 mm		203mm x 254mm
	SMFP100200	100 mm × 200 mm	68030	170mm x 237mm		203mm x 406mm
	SMFP100300	100 mm × 300 mm	88030	190 mm x 330 mm		232mm x 648mm
	SMFP150300	150 mm × 300 mm	88035	254mm x 356 mm		254mmx 381mm
	SMFP200400	200 mm × 400 mm	68035	305 mm x 432 mm		267 mmx 211mm
	SMFP250450	250 mm × 450 mm	88040	230mm x 305mm		305mm x 381mm
	SMFP300500	300 mm × 500 mm	68040	285mm x 370mm		305 mmx 457mm
						330mm x 381mm
						330 mmx 457mm
						406mm x 406mm
						457mm x 559mm

	SMGP100300	100 mm × 40 mm× 300 mm	N/A	N/A
	SMGP150400	150 mm × 50 mm× 400 mm		
	SMGP200400	200 mm × 50 mm× 400 mm		
	SMGP250480	250 mm × 60 mm× 480 mm		
	SMGP300500	300 mm × 70 mm× 500 mm		
	SMFR 022	50 mm × 200 M		
	SMFR 032	75 mm × 200 M		
	SMFR 042	100 mm × 200 M		
	SMFR 062	150 mm × 200 M		
	SMFR 082	200 mm × 200 M		
	SMFR 102	250 mm × 200 M		
	SMFR 122	300 mm × 200 M		
	SMFR 142	350 mm × 200 M		
	SMFR 162	400 mm × 200 M		
	SMGR 031	75 mm × 35 mm ×100 M		
	SMGR 041	100 mm × 40 mm ×100M		
	SMGR 061	150 mm × 50 mm ×100 M		
	SMGR 081	200 mm × 50 mm ×100 M		
	SMGR 101	250 mm × 60 mm ×100 M		
	SMGR 121	300 mm × 70 mm ×100 M		
	SMGR 141	350 mm × 80 mm ×100 M		
	SMGR 161	400 mm × 80 mm ×100 M		
Sterilization cycles	The recommended steam sterilization cycle parameters are 30 minutes at 121℃. The recommended EO sterilization cycle is 4 hours at 55℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.		The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 100 – 120 minutes at 50 0C with a relative humidity between 60 - 85% and a sterilant concentration of 600 mg/L.	It is to be sterilized by a health provider by steam 121°C for 15 minutes or ethylene oxide (EtO).
Design features	**Self-sealing sterilization pouches:** These pouches are made from a medical grade plastic film that is heat sealed on three sides. ~~The forth side has an adhesive strip~~ that is used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before seal ~~the pouch. The medical grade paper~~ conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas.		The pouches are manufactured from a medical grade paper that is thermally sealed to a ~~laminated film on the left,~~ right, and bottom of pouch. The forth side has an adhesive strip that is used to seal the paper to the film prior to sterilization of the enclosed medical device. ~~The pouches contain external~~ indicators used to indicate the pouches were processed via steam or EO sterilization.	These pouches are manufactured from a medical grade paper and ~~plastic film that are heat~~ sealed on three sides. The forth side has an adhesive strip that is used to seal pouch. The medical grade paper conform to ~~recognized material~~ standards and can be sterilized by team or ethylene oxide gas.

	Sterilization pouches, Flat: These pouches has the same components with the Self-sealing sterilization pouches, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using. **Sterilization pouches, Gusseted:** These pouches are the same with the Sterilization pouches, flat, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height. **Sterilization rolls, Flat:** These rolls are made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the self-sealing sterilization pouches. **Sterilization rolls, Gusseted:** These rolls are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.	N/A	N/A

CONCLUSION:

The SIGMA sterilization pouch and roll, Medicom Self Sealing sterilization pouch and Winner® Self Seal Sterilization pouch are all intended for provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO).

The SIGMA sterilization pouch and roll has many similar technological characteristics when compared to the predicate devices. The material composition of SIGMA sterilization pouch and roll is similar to the predicate devices. Besides parameters of sterilization, the intended use of SIGMA sterilization pouch and roll is similar to the predicate devices. The first type of SIGMA sterilization pouch and roll is Self-sealing sterilization pouches. The device models and design features of Self-sealing sterilization pouches are similar to the predicate devices. The design features that SIGMA sterilization pouch and roll's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process is also similar to the predicate devices.

The SIGMA sterilization pouch and roll has some different design features from the predicate device. The SIGMA sterilization pouch and roll is offered 5 types pouches. The first type of SIGMA sterilization pouch and roll is Self-sealing sterilization pouches. And the design features of Self-sealing sterilization pouches are similar to the predicate devices. The second type of SIGMA sterilization pouch and roll is Sterilization pouches, Flat. "The Sterilization pouches, Flat" has the same components with the Self-sealing sterilization pouches, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using. The third type of SIGMA sterilization pouch and roll is Sterilization pouches, Gusseted. "The Sterilization pouches, Gusseted" are the same with the "Sterilization pouches, flat", except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height. The fourth type of SIGMA sterilization pouch and roll is Sterilization rolls, Flat. "The Sterilization rolls, Flat" are made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the self-sealing sterilization pouches. The fifth type of SIGMA sterilization pouch and roll is Sterilization rolls, Gusseted. "The Sterilization rolls, Gusseted" are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.

Effectiveness and Safety

The SIGMA sterilization pouch and roll has the identical intended use and indication for use as the predicate devices. Substantial equivalence to predicate devices was established by testing the Sterilant Penetration, Drying Time, Aeration, Biocompatibility, Package Integrity, Material Compatibility, Sterility Maintenance, and Chemical Indicator Efficacy.

The SIGMA sterilization pouch and roll validates its effectiveness and safety using recommended practice, standards and guidelines developed by independent organizations such as the Association for the advancement of Medical Instrumentation (AAMI), International Organization for Standardization (ISO), and American Society for Testing and Materials (ASTM). The SIGMA sterilization pouch and roll was validated to meet the requirements of ANSI/AAMI/ISO 11607-1:2006, Version three, September 2008.

The results of the SIGMA sterilization pouch and roll validation studies demonstrate that the sterilization pouches perform as intended. The results are summarized as follows:

- The Sterilant Penetration, Drying Time, Aeration, testing performed as described in AAMI / ANSI / ISO 17665-1:2006, ISO TS 17665-2:2009, AAMI / ANSI / ISO 11135-1:2007, and AAMI / ANSI / ISO 10993-7:2008. The testing results demonstrate the ability of the Sigma Sterilization Pouch and Roll to effectively adequate sterilant penetration to the most difficult areas to reach inside the packaging. The results confirm that the sterilant is able to penetrate the Sigma Sterilization Pouch and Roll and sustain direct contact with the medical instrument inside the package. And the result of aeration time validation test meets the requirements AAMI / ANSI / ISO 10993-7:2008.
- The Biocompatibility testing performed as described in ISO 10993-10:2010(E), ISO 10993-1:2009/Cor. 1:2010(E), ISO 10993-12:2007(E), and ISO/IEC 17025:2005. The testing results demonstrate the Sigma Sterilization Pouch and Roll showed "negative reaction". And the SIGMA sterilization pouch and roll meets the requirements ISO 10993-10:2010(E).
- The Package Integrity, Material Compatibility, Sterility Maintenance testing performed as described in AAMI / ANSI / ISO 11607-1:2006, ISO 1924-2, ISO 5636-3, ASTM D 3078-02, ASTM D882, ASTM F 2251-03, ASTM D 1004, ASTM F 1140-07, ASTM F 1929-98 (04), ASTM F 88-2007, ASTM F 1980-2007, ASTM F 1980-2007, and ASTM F 1608-00. The testing results demonstrate the ability of the Sigma Sterilization Pouch and Roll to effectively adequate Package Integrity.
- The Chemical Indicator Efficacy testing performed as described in AAMI / ANSI / ISO 11140-1:2005. The testing demonstrates the ability of the Sigma Sterilization Pouch and Roll to effectively stability of the Process Indicators Ink before use, the lasting quality (color stability) of the color change, the completeness and uniformity of the color change and color change is all or none at the conditions measured, unless a color standard is provided on the indicator. And the SIGMA sterilization pouch and roll meets the requirements ISO 11140-1:2005.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sigma Medical Supplies Corporation
C/O Ms. Uta Shih
Regulatory Affairs Manager
Sen Mu Technology Company, Limited
15-2, LN 26, Mineyuan 1st Road
Lingya District
Kaohsiung
China (Taiwan) 802

AUG - 2 2011

Re: K102158
Trade/Device Name: SIGMA Sterilization Pouch and Roll
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: July 20, 2011
Received: July 27, 2011

Dear Ms. Shih:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRH Offices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number: **K102158**

Device Name: SIGMA sterilization pouch and roll

Indications for Use:

The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121℃. The recommended EO sterilization cycle is 4 hours at 55℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 3 years post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.

The SIGMA sterilization pouch and roll is offered in the following 5 types:

- Self-sealing sterilization pouches
- Sterilization pouches, Flat
- Sterilization pouches, Gusseted
- Sterilization rolls, Flat
- Sterilization rolls, Gusseted

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine S. Marshall for EPC
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102158

The defining characteristics of the 5 types as follows:

- **Self-sealing sterilization pouches:** These pouches are made from a medical grade plastic film that is heat sealed on three sides. The forth side has an adhesive strip that is used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas.
- **Sterilization pouches, Flat:** These pouches has the same components with the Self-sealing sterilization pouches, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using.
- **Sterilization pouches, Gusseted:** These pouches are the same with the Sterilization pouches, flat, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.
- **Sterilization rolls, Flat:** These rolls are made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the self-sealing sterilization pouches.
- **Sterilization rolls, Gusseted:** These rolls are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.

The following table (**Table 2-1**) lists the model numbers of the SIGMA sterilization pouch and roll by type, model, dimension and characteristics:

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Table 2-1 The model numbers of SIGMA sterilization pouch and roll (Type, Model, Dimension and Characteristics)

Type	Model	Dimension in S.I.	Characteristics
Self-Sealing Sterilization Pouches	SMSE057133	57 mm × 133 mm	These pouches are made from a medical grade plastic film that is heat-sealed on three sides. The forth side has an adhesive strip that is paper and used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas.
	SMSE090162	90 mm × 162 mm	
	SMSE070257	70 mm × 257mm	
	SMSE090257	90 mm × 257 mm	
	SMSE135283	135 mm × 283 mm	
	SMSE180335	135 mm × 335 mm	
	SMSE190358	190 mm × 358 mm	
	SMSE300380	300 mm × 380 mm	
	SMSE300474	300 mm × 474 mm	
Sterilization Pouches, Flat	SMFP075200	75 mm × 200 mm	These pouches has the same components with the Self-sealing sterilization pouches, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using.
	SMFP075300	75 mm × 300 mm	
	SMFP100200	100 mm × 200 mm	
	SMFP100300	100 mm × 300 mm	
	SMFP150300	150 mm × 300 mm	
	SMFP200400	200 mm × 400 mm	
	SMFP250450	250 mm × 450 mm	
	SMFP300500	300 mm × 500 mm	
Sterilization Pouches, Gusseted	SMGP100300	100 mm × 40 mm× 300 mm	These rolls are the same with the Sterilization pouches, flat, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.
	SMGP150400	150 mm × 50 mm× 400 mm	
	SMGP200400	200 mm × 50 mm× 400 mm	
	SMGP250480	250 mm × 60 mm× 480 mm	
	SMGP300500	300 mm × 70 mm× 500 mm	
Sterilization Rolls, Flat	SMFR 022	50 mm × 200 M	These rolls are made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the self-sealing sterilization pouches.
	SMFR 032	75 mm × 200 M	
	SMFR 042	100 mm × 200 M	
	SMFR 062	150 mm × 200 M	
	SMFR 082	200 mm × 200 M	
	SMFR 102	250 mm × 200 M	
	SMFR 122	300 mm × 200 M	
	SMFR 142	350 mm × 200 M	
	SMFR 162	400 mm × 200 M	
Sterilization Rolls, Gusseted	SMGR 031	75 mm × 35 mm ×100 M	These rolls are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.
	SMGR 041	100 mm × 40 mm ×100M	
	SMGR 061	150 mm × 50 mm ×100 M	
	SMGR 081	200 mm × 50 mm ×100 M	
	SMGR 101	250 mm × 60 mm ×100 M	
	SMGR 121	300 mm × 70 mm ×100 M	
	SMGR 141	350 mm × 80 mm ×100 M	
	SMGR 161	400 mm × 80 mm ×100 M	